I

103D CONGRESS
1ST SESSION

H. R. 2910

To more fully and accurately inform the public concerning health, safety, and environmental risks, to improve consistency in the presentation of scientific information, and to enhance the scientific credibility of the regulatory decisions of the Environmental Protection Agency.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 6, 1993

Mr. MOORHEAD (for himself, Mr. BROWN of California, Mr. BLILEY, Mr. OXLEY, Mr. HAYES, Mrs. LLOYD, Mr. WALKER, and MR. ZIMMER) introduced the following bill; which was referred jointly to the Committees on Science, Space, and Technology and Energy and Commerce

---

A BILL

To more fully and accurately inform the public concerning health, safety, and environmental risks, to improve consistency in the presentation of scientific information, and to enhance the scientific credibility of the regulatory decisions of the Environmental Protection Agency.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Risk Communication Act of 1993''.

SEC. 2. PURPOSES.

The purposes of this Act are—

(1) to present the public and Environmental Protection Agency officials with the most scientifically objective information concerning the nature and magnitude of health, safety, and environmental risks in order to provide for sound regulatory decisions and public education;

(2) to provide for full consideration and discussion of relevant data and potential methodologies;

(3) to require explanation of significant choices in the risk assessment process which will allow for better peer review and public understanding; and

(4) to improve consistency within the Environmental Protection Agency in preparing risk assessments and risk characterizations.

SEC. 3. EFFECTIVE DATE; APPLICABILITY; SAVINGS PROVISIONS.

(a) EFFECTIVE DATE.—Except as otherwise specifically provided in this Act, the provisions of this Act shall take effect 2 years after the date of enactment of this Act.

(b) APPLICABILITY.—(1) Except as provided in paragraph (2), this Act applies to all risk assessments and risk characterizations prepared by or on behalf of the Environmental Protection Agency in connection with health, safety, and environmental risks.

(2) This Act does not apply to risk assessments or risk characterizations performed with respect to a situation that the Administrator considers to be an emergency.

(c) SAVINGS PROVISIONS.—Nothing in this Act shall be construed to modify any statutory standard or requirement designed to protect health, safety, or the environment.

SEC. 4. PRINCIPLES FOR RISK ASSESSMENT.

(a) IN GENERAL.—The Administrator of the Environmental Protection Agency shall apply the principles set forth in subsection (b) when preparing risk assessments in order to assure that such risk assessments and all of their components are, to the maximum extent possible, scientifically objective and inclusive of all relevant data. Discussions or explanations required under this section need not be repeated in each risk assessment document as long as there is a reference to the relevant discussion or explanation in another agency document.

(b) PRINCIPLES.—The principles to be applied when preparing risk assessments are the following:

(1) The Administrator shall explicitly distinguish scientific findings in risk assessments from other considerations affecting the design and choice of regulatory strategies.

(2) The Administrator shall consider and discuss both negative and positive laboratory or epidemiological data of sufficient quality when presenting assessments of human health risks. Where conflicts among such data appear to exist, the assessment shall include discussion of possible reconciliation of conflicting information, which may include differences in study designs, comparative physiology, routes of exposure, bioavailability, pharmacokinetics, and any other relevant factor.

(3) Where the risk assessment process involves selection of any significant assumption, inference, or model the Administrator shall (A) present a representative list and explanation of plausible and alternative assumptions, inferences, or models; (B) explain the basis for any choices; and (C) identify any policy or value judgments. The Administrator shall also indicate the extent to which any significant model has been validated by or conflicts with empirical data.

SEC. 5. PRINCIPLES FOR RISK CHARACTERIZATION.

In characterizing risk in any risk assessment document, regulatory proposal or decision, report to Congress, or other document which is made available to the public, the Administrator shall comply with each of the following:

(1) The Administrator shall characterize the populations or natural resources at risk. If a numerical estimate of risk is provided, the departments and agencies shall, to the extent feasible, provide the best estimate or estimates for the populations or natural resources at risk, given the information available to the Administrator, along with a statement of the reasonable range of scientific uncertainty. In addition to the best estimate, the Administrator may present plausible upper-bound or conservative estimates in conjunction with plausible lower bounds estimates. Where appropriate, the Administrator may present, in lieu of a single best estimate, multiple estimates based on assumptions, inferences, or models which are equally plausible, given current scientific understanding.

(2) The Administrator shall explain the range of exposure scenarios used in any risk assessment, and, to the extent feasible, provide a statement of the size of the corresponding population at risk and the likelihood of such exposure scenarios.

(3) To the extent feasible, the Administrator shall provide appropriate comparisons with estimates of other risks, including those that are familiar to and routinely encountered by the general public.

(4) When the Administrator provides a risk assessment or risk characterization for proposed and final regulatory actions, such assessment or characterization shall include a statement of any known and significant substitution risks.

(5) In any case in which the Administrator provides a public comment period with respect to a risk assessment or regulation, and a commenter provides a risk assessment and summary of results that is consistent with the principles and the guidance provided under this Act, the Administrator shall present the summary of results of such risk assessment in connection with the presentation of the Environmental Protection Agency's risk assessment (if any) or regulation.

SEC. 6. GUIDANCE, PLAN FOR ASSESSING NEW INFORMATION, AND REPORT.

(a) GUIDANCE.—Within 18 months after the date of enactment of this Act, the Administrator shall issue guidance consistent with the risk assessment and characterization principles stated in sections 4 and 5 and shall provide a format for summarizing risk assessment results.

(b) ADDITIONAL SUBJECTS ADDRESSED.—In addition to including the principles set forth in sections 4 and 5, the guidance issued under this section shall include

guidance on at least the following subjects: interspecies scaling factors; use of different types of dose-response models; thresholds; definitions, use, and interpretations of the maximum tolerated dose; weighting of positive and negative findings from sensitive species; evaluation of benign tumors, and evaluation of different health endpoints.

(c) PLAN.—Within 2 years after the date of enactment of this Act, the Administrator shall publish a plan to review and revise any risk assessment with respect to which the Environmental Protection Agency determines there is significant new information or methodologies available that could significantly alter the prior results of the risk assessment. The plan shall provide procedures for receiving and considering new information and risk assessments from the public. The plan may set priorities for review and revision of risk assessments based on factors the Administrator considers appropriate.

(d) REPORT.—Within 3 years after the enactment of this Act, the Administrator shall provide a report to the Congress evaluating the policy and value judgments of the type identified under paragraph (3) of section 4 which are made by the Administrator in risk assessments performed for programs under the Toxic Substances Control Act and the effect these judgments have on the regulatory decisions of such programs.

(e) PUBLIC COMMENT AND CONSULTATION.—The guidance, plan and report under this section, shall be developed after notice and opportunity for public comment and in consultation with the EPA Science Advisory Board, representatives of appropriate State agencies, and such other departments and agencies, offices, organizations, or persons as the Administrator considers advisable.

(f) REVIEW.—Guidance promulgated under this section shall be reviewed by the Administrator at least every 4 years in accordance with subsection (d).

SEC. 7. DEFINITIONS.

For purposes of this Act:

(1) The term ''risk assessment'' means the process of identifying hazards and quantifying or describing the degree of risk they pose for exposed individuals, populations, or resources. It also refers to the document containing the explanation of how the assessment process has been applied to an individual substance, activity, or condition.

(2) The term ''risk characterization'' means that element of a risk assessment that involves presentation of the degree of risk in any regulatory proposal or decision, report to Congress, or other document which is made available to the public. The term includes discussions of uncertainties, conflict-

ing data, estimates, extrapolations, inferences, and opinions.

(3) The term ''best estimate'' means an estimate based on (A) central estimates of risk using the most unbiased assumptions and models, (B) an approach which combines multiple estimates based on different scenarios and weighs the probability of each scenario or (C) any other methodology designed to provide the most unbiased representation of the most plausible level of risk, given the current scientific information available to the Administrator.

(4) The term ''negative data'' means data indicating that under certain conditions a given substance or activity did not induce an adverse effect.

(5) The term ''substitution risk'' means a potential increased risk to human health, safety, or the environment from a regulatory option designed to decrease other risks.

○